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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/701,680 | 11/29/2000 | Ryuzo Hosotani | YANAGIHARA | 7997 |

7590 06/16/2004

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| EXAMINER |
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WHITE, EVERETT NMN

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1623

DATE MAILED: 06/16/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,680

Applicant(s)

HOSOTANI ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 26, 2003 has been entered.

2. The amendment filed July 28, 2003 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

- (A) Claims 1-11 have been canceled;
- (B) New Claim 15 has been added;
- (C) Claims 12-14 have been amended;
- (D) Comments regarding Office Action have been provided drawn to:
 - (i) 103(a) rejection, rendered moot by new ground of rejection over newly cited US Patent.

3. Claims 12-15 are pending in the case.

4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

5. Claims 12-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shiku et al (WO 98/09650) or Macromolecules, 3062 (1993) in view of Lander (US Patent No. 6,410,025) or Okumura et al (US Patent No. 5,272,053) for the reasons set forth on pages 2-4 of the Office Action mailed February 26, 2003 (paper No. 7).

6. Applicant's arguments filed July 28, 2003 have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon

Art Unit: 1623

hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicants further argue that in order to produce the aggregates of a hydrophobic group-containing polysaccharide according to the present invention, specific process steps are required, which include the starting hydrophobic group-containing polysaccharide being swollen with water in order to form an aqueous dispersion and the swollen dispersion being treated using a high pressure homogenizer, causing the dispersion to be discharged under a pressure of from 9.8 to 490 MPa through an orifice into a chamber to obtain a monodispersed dispersion of aggregates of 10-30 nanometer diameter of the polysaccharide molecules wherein the molecules of the polysaccharide have an association number of 3-20. This argument is not persuasive because the Lander patent sets forth the process steps disclosed in the instant claims, as previously indicated, that involves dissolving polysaccharides in water and then size reducing the polysaccharides by passing the polysaccharides through a high pressure orifice using a mechanical homogenizer, which produces a reduced sized, monodisperse polysaccharide (see column 3, 2nd paragraph) as instantly claimed. See Example 1 of the Lander patent whereby the polysaccharide solution is subjected to a high pressure homogenization at pressures ranging from 3,000 to 14,000 psi, which falls within the pressure range set forth in the instant claims. The Lander patent uses a high-pressure homogenizer that is analogous to the high-pressure homogenizer used in the instant claims. The combination of the Lander patent with the other cited references (i.e., the Shiku et al patent or the Macromolecules reference in view of the Lander patent or the Okumura et al patent) shows that the other characteristics disclosed in the claims (i.e., the recited particle size, polysaccharide, formula) are not distinct and would be obvious under 35 U.S.C. 103. Accordingly, the rejection of Claims 12-15 under 35 U.S.C. 103 as being unpatentable over the Shiku et al patent or the Macromolecules reference in view of the Lander patent or the Okumura et al patent is maintained for the reasons of record.

Summary

7. All the pending claims are rejected.

Conclusion

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

9. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

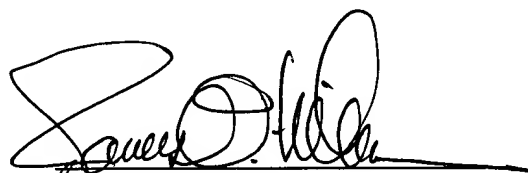
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

Art Unit: 1623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E.White



James O. Wilson
Supervisory Primary Examiner
Technology Center 1600